K061551

ATTACHMENT 2

AUG 24 2006

SPECIAL 510(k) SUMMARY

1.0 Modified Device Identification:

Trade Name	:	1) Safety + Comfort, and 2) Multiple or Customers' Trade Name
Device Name	:	Powder Free Latex Examination Gloves, Natural or Blue Colour and with Protein Content Labeling Claim (50 Micrograms or Less)
Common Name	:	Examination Gloves
Classification Name	:	Patient Examination Gloves (per 21 CFR 880.6251)

2.0 Submitter:

Name	:	Medipure Corporation (M) Sdn Bhd
Address	:	Lot 12, Medan Tasek, Tasek Industrial Estate, 31400 Ipoh, Perak Darul Ridzuan, MALAYSIA
Phone #	:	+60 5 291 0060
Fax #	:	+60 5 291 0051
FDA Registration #	:	8041177
Device Listing #	:	A722779

Date of Summary Prepared: May 24, 2006

3.0 Contact Person:

Name	:	Mr. Terence Lim Sin Kooi
Phone #	:	+60 5 291 0060
Fax #	:	+60 5 291 0051

4.0 Identification of the Legally Marketed Device:

Class I powder free natural rubber latex examination gloves, 80LYY meets all the requirements of ASTM standard D 3578 – 05 and FDA 21 CFR 800.20.

5.0 Predicate Device Information:

Unmodified Device Name	:	Latex Patient Examination Gloves, Powder Free
Cleared 510(k)	:	K924356
Date Approved	:	February 3, 1994

6.0 Description of Device Modification:

The Powder Free Latex Examination Gloves, Natural or Blue Colour and with Protein Content Labeling Claim is equivalent to the exiting model, i.e. Latex Patient Examination Gloves, Powder Free which had submitted and cleared under 510(k) number K924356.

The differences in this submission are:

a) With or without colour additive upon customers' preference or request.
b) With protein content labeling claim, i.e. "This latex glove contains 50 micrograms or less of total water extractable protein per gram".

All the above options will be subjected to design controls process, whereby risk assessment will be conducted to identify the potential hazards and estimate the risks of colour changed (Refer to Section 5 – Design Control Activities for the modified Device).

The modification of device does not affect the intended use of the device as well as it does not affect its safety and effectiveness.

7.0 Intended Use of the Device:

The Powder Free Latex Examination Glove, Natural or Blue Colour and with Protein Content Labeling Claim is a disposable device made of natural rubber latex and is intended to be worn on hands to provide barrier against potentially infectious materials and other contaminants on medical purposes.

The indication for use and proposed labeling for the device are illustrated in sections 3 & 4.

8.0 Device Description and Comparison:

The device description and comparison between unmodified and modified device, i.e. Powder Free Latex Examination Gloves, Natural or Blue Colour and with Protein Content Labeling Claim are as follows.

Table 1

	Device Name	
	Unmodified device	Modified Device
510 (K) Number	K924356	K061551
Device Listing Number	A722779	A722779
Proprietary Name	Multiple or Customers' Trade Name	Safety + Comfort and Multiple or Customers' Trade Name
Product Code	80LYY	80LYY
Classification Name	Patient examination gloves, powder free (per 21 CFR 880.6251)	Patient examination gloves, powder free (per 21 CFR 880.6251)
Intended Use	Provide barrier against potentially infectious materials and other contaminants	Provide barrier against potentially infectious materials and other contaminants
Composition of gloves	Natural rubber latex	Natural rubber latex
Color Additive	Without color additive	With or without colour additive
Protein Content Labeling Claim	Without protein content labeling claim	With protein content labeling claim
Compliance with ASTM standards	ASTM D3578 ASTM D6124	ASTM D3578 ASTM D6124 ASTM D5712
Compliance with other standards	FDA 21 CFR 800.20	FDA 21 CFR 800.20
Labeling	21 CFR 820.120	21 CFR 820.120

Table 2

Characteristics	Standards	Device Name		Device Performance
		Unmodified device	Modified Device	
Palm Width (Medium)	ASTM D 3578	90 – 91 mm	91 – 92 mm	Meets
Length (Medium)	ASTM D 3578	285 – 290 mm	285 – 292 mm	Meets
Finger Thickness (Medium)	ASTM D 3578	0.31 – 0.32 mm	0.38 – 0.40	Meets
Palm Thickness (Medium)	ASTM D 3578	0.25 – 0.26 mm	0.35 – 0.37 mm	Meets
Tensile Strength (Unaged)	ASTM D 3578	19.04 – 32.10 MPa	22.88 – 30.87 MPa	Meets
Tensile Strength (Aged)	ASTM D 3578	16.40 – 18.35 MPa	21.05 – 27.60 MPa	Meets
Freedom from pinholes	ASTM D 3578 FDA 21 CFR 800.20	1/125	0/125	Meets
Visual Inspection - Major defects	In-House Specification	0/125	1/125	Meets (AQL 2.5)
Visual Inspection - Minor defects	In-House Specification	1/125	1/125	Meets (AQL 4.0)
Powder Residual	ASTM D 3578 ASTM D 6124	Avg. 1.63 mg/glove	Avg. 0.96 mg/glove.	Meets < 2 mg/glove
Protein Content	ASTM D 3578 ASTM D 5712	21 – 24 µg/g	17 – 29 µg/g	Meets < 50 µg/g
Biocompatability - Primary Skin Irritation	16 CFR Part 1500	Not a primary skin irritant	Not a primary skin irritant	Meets (Non Irritant)
Biocompatability - Dermal Sensitization	Buehler Method	Not a contact sensitizer	Not a contact sensitizer	Meets (Non Sensitizer)

9.0 Conclusion:

The Powder Free Latex Examination Gloves, Natural or Blue Colour and with Protein Content Labeling Claim (50 Micrograms or Less) will perform according to the glove performance standards as above and meet ASTM standards, and FDA requirements for waterleak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2006

Mr. Terence Lim Sin Kooi
Senior Quality Assurance/Regulatory Affairs Manager
Medipure Corporation (M) SDN. BHD.
Lot 12, Medan Tasek
Tasek Industrial Estate,
Ipoh Perak 31400
MALAYSIA

Re: K061551
Trade/Device Name: Powder Free Latex Examination Gloves, Natural or blue Colour and with Protein Content labeling Claim (50 Micrograms or less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 15, 2006
Received: August 17, 2006

Dear Mr. Kooi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

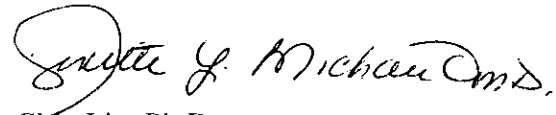
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: POWDER FREE LATEX EXAMINATION GLOVES, NATURAL OR BLUE COLOUR AND WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

Indications For Use:

The Powder Free Latex Examination Glove is a disposable device made of natural rubber latex that may bear a trace amount of glove powder and is intended to be worn on hands or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

Sheila M Murphy MD 8/24/04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K061551

Prescription Use _____ AND/OR Over-The-Counter Use X
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)